

Subpart E—Testing Requirements for Communicable Disease Agents

§ 610.40 Test requirements.

(a) *Human blood and blood components.* Except as specified in paragraphs (c) and (d) of this section, you, an establishment that collects blood or blood components, must test each donation of human blood or blood component intended for use in preparing a product, including donations intended as a component of, or used to prepare, a medical device, for evidence of infection due to the following communicable disease agents:

- (1) Human immunodeficiency virus, type 1;
- (2) Human immunodeficiency virus, type 2;
- (3) Hepatitis B virus;
- (4) Hepatitis C virus;
- (5) Human T-lymphotropic virus, type I; and
- (6) Human T-lymphotropic virus, type II.

(b) *Testing using one or more approved screening tests.* To test for evidence of infection due to communicable disease agents designated in paragraph (a) of this section, you must use screening tests that the Food and Drug Administration (FDA) has approved for such

use, in accordance with the manufacturer's instructions. You must perform one or more such tests as necessary to reduce adequately and appropriately the risk of transmission of communicable disease.

(c) *Exceptions to testing for allogeneic transfusion or further manufacturing use—(1) Dedicated donations.* (i) You must test donations of human blood and blood components from a donor whose donations are dedicated to and used solely by a single identified recipient under paragraphs (a), (b), and (e) of this section; except that, if the donor makes multiple donations for a single identified recipient, you may perform such testing only on the first donation in each 30-day period. If an untested dedicated donation is made available for any use other than transfusion to the single, identified recipient, then this exemption from the testing required under this section no longer applies.

(ii) Each donation must be labeled as required under § 606.121 of this chapter and with a label entitled "INTENDED RECIPIENT INFORMATION LABEL" containing the name and identifying information of the recipient. Each donation must also have the following label, as appropriate:

Donor Testing Status	Label
Tests negative	Label as required under § 606.121
Tested negative within the last 30 days	"DONOR TESTED WITHIN THE LAST 30 DAYS"

(2) *Source Plasma.* You are not required to test donations of Source Plasma for evidence of infection due to the communicable disease agents listed in paragraphs (a)(5) and (a)(6) of this section.

(3) *Medical device.* (i) You are not required to test donations of human blood or blood components intended solely as a component of, or used to prepare, a medical device for evidence of infection due to the communicable disease agents listed in paragraphs (a)(5) and (a)(6) of this section unless the final device contains viable leukocytes.

(ii) Donations of human blood and blood components intended solely as a

component of, or used to prepare, a medical device must be labeled "Caution: For Further Manufacturing Use as a Component of, or to Prepare, a Medical Device."

(4) *Samples.* You are not required to test samples of blood, blood components, plasma, or sera if used or distributed for clinical laboratory testing or research purposes and not intended for administration to humans or in the manufacture of a product.

(d) *Autologous donations.* You, an establishment that collects human blood or blood components from autologous donors, or you, an establishment that

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is a consignee of a collecting establishment, are not required to test donations of human blood or blood components from autologous donors for evidence of infection due to communicable disease agents listed in paragraph (a) of this section or by a serological test for syphilis under paragraph (i) of this section, except:

(1) If you allow any autologous donation to be used for allogeneic transfusion, you must assure that all autologous donations are tested under this section.

(2) If you ship autologous donations to another establishment that allows

autologous donations to be used for allogeneic transfusion, you must assure that all autologous donations shipped to that establishment are tested under this section.

(3) If you ship autologous donations to another establishment that does not allow autologous donations to be used for allogeneic transfusion, you must assure that, at a minimum, the first donation in each 30-day period is tested under this section.

(4) Each autologous donation must be labeled as required under § 606.121 of this chapter and with the following label, as appropriate:

Donor Testing Status	Label
Untested	"DONOR UNTESTED"
Tests negative	Label as required under § 606.121
Reactive on current collection/reactive in the last 30 days	"BIOHAZARD" legend in § 610.40(h)(2)(ii)(B)
Tested negative within the last 30 days	"DONOR TESTED WITHIN THE LAST 30 DAYS"

(e) *Further testing.* You must further test each donation, including autologous donations, found to be reactive by a screening test performed under paragraphs (a) and (b) of this section, whenever a supplemental (additional, more specific) test has been approved for such use by FDA, except:

(1) For autologous donations, you must further test under this paragraph, at a minimum, the first reactive donation in each 30-day period; or

(2) If you have a record for that donor of a positive result on a supplemental (additional, more specific) test approved for such use by FDA, you do not have to further test an autologous donation.

(f) *Testing responsibility.* Required testing under this section, must be performed by a laboratory registered in accordance with part 607 of this chapter and either certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) under 42 CFR part 493 or has met equivalent requirements as determined by the Health Care Financing Administration in accordance with those provisions.

(g) *Release or shipment prior to testing.* Human blood or blood components that are required to be tested for evidence of infection due to communicable dis-

ease agents designated in paragraphs (a) and (i) of this section may be released or shipped prior to completion of testing in the following circumstances provided that you label the blood or blood components under § 606.121(h) of this chapter, you complete the tests for evidence of infection due to communicable disease agents as soon as possible after release or shipment, and that you provide the results promptly to the consignee:

(1) Only in appropriately documented medical emergency situations; or

(2) For further manufacturing use as approved in writing by FDA.

(h) *Restrictions on shipment or use—(1) Reactive screening test.* You must not ship or use human blood or blood components that have a reactive screening test for evidence of infection due to a communicable disease agent(s) designated in paragraphs (a) and (i) of this section or that are collected from a donor with a previous record of a reactive screening test for evidence of infection due to a communicable disease agent(s) designated in paragraphs (a) and (i) of this section, except as provided in paragraphs (h)(2)(i) through (h)(2)(vii) of this section.

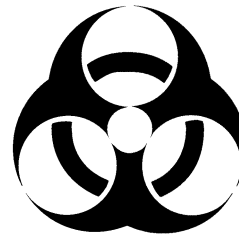
(2) *Exceptions.* (i) You may ship or use blood or blood components intended for

autologous use, including reactive donations, as described in paragraph (d) of this section.

(ii) You must not ship or use human blood or blood components that have a reactive screening test for evidence of infection due to a communicable disease agent(s) designated in paragraph (a) of this section or that are collected from a donor deferred under § 610.41(a) unless you meet the following conditions:

(A) Except for autologous donations, you must obtain from FDA written approval for the shipment or use;

(B) You must appropriately label such blood or blood components as required under § 606.121, or § 640.70 of this chapter, and with the "BIOHAZARD" legend;



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(C) Except for autologous donations, you must label such human blood and blood components as reactive for the appropriate screening test for evidence of infection due to the identified communicable disease agent(s);

(D) If the blood or blood components are intended for further manufacturing use into injectable products, you must include a statement on the container label indicating the exempted use specifically approved by FDA.

(E) Each blood or blood component with a reactive screening test and intended solely as a component of, or used to prepare a medical device, must be labeled with the following label, as appropriate:

Type of Medical Device	Label
A medical device other than an in vitro diagnostic reagent	"Caution: For Further Manufacturing Use as a Component of a Medical Device For Which There Are No Alternative Sources"
An in vitro diagnostic reagent	"Caution: For Further Manufacturing Into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources"

(iii) The restrictions on shipment or use do not apply to samples of blood, blood components, plasma, or sera if used or distributed for clinical laboratory testing or research purposes, and not intended for administration in humans or in the manufacture of a product.

(iv) You may use human blood or blood components from a donor with a previous record of a reactive screening test(s) for evidence of infection due to a communicable disease agent(s) designated in paragraph (a) of this section, if:

(A) At the time of donation, the donor is shown or was previously shown to be suitable by a requalification method or process found accept-

able for such purposes by FDA under § 610.41(b); and

(B) tests performed under paragraphs (a) and (b) of this section are nonreactive.

(v) Anti-HBc reactive donations, otherwise nonreactive when tested as required under this section, may be used for further manufacturing into plasma derivatives without prior FDA approval or a "BIOHAZARD" legend as required under paragraphs (h)(2)(ii)(A) and (h)(2)(ii)(B) of this section.

(vi) You may use human blood or blood components, excluding Source Plasma, that test reactive by a screening test for syphilis as required under paragraph (i) of this section if, consistent with § 640.5 of this chapter, the

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donation is further tested by an adequate and appropriate test which demonstrates that the reactive screening test is a biological false positive. You must label the blood or blood components with both test results.

(vii) You may use Source Plasma from a donor who tests reactive by a screening test for syphilis as required under § 610.40(i) of this chapter, if the donor meets the requirements of § 640.65(b)(2) of this chapter.

(i) *Syphilis testing.* In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§ 640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a), and 640.65(b)(2) of this chapter.

[66 FR 31162, June 11, 2001]

§ 610.41 Donor deferral.

(a) You, an establishment that collects human blood or blood components, must defer donors testing reactive by a screening test for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) or reactive for a serological test for syphilis under § 610.40(i), from future donations of human blood and blood components, except:

(1) You are not required to defer a donor who tests reactive for anti-HBc or anti-HTLV, types I or II, on only one occasion. When a supplemental (additional, more specific) test for anti-HBc or anti-HTLV, types I and II, has been approved for use under § 610.40(e) by FDA, such a donor must be deferred;

(2) A deferred donor who tests reactive for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) may serve as a donor for blood or blood components shipped or used under § 610.40(h)(2)(ii);

(3) A deferred donor who showed evidence of infection due to hepatitis B surface antigen (HBsAg) when previously tested under § 610.40(a), (b), and (e) subsequently may donate Source Plasma for use in the preparation of Hepatitis B Immune Globulin (Human) provided the current donation tests nonreactive for HBsAg and the donor is otherwise determined to be suitable;

(4) A deferred donor, who otherwise is determined to be suitable for donation and tests reactive for anti-HBc or for evidence of infection due to HTLV,

types I and II, may serve as a donor of Source Plasma;

(5) A deferred donor who tests reactive for a communicable disease agent(s) described under § 610.40(a) or reactive with a serological test for syphilis under § 610.40(i), may serve as an autologous donor under § 610.40(d).

(b) A deferred donor subsequently may be found to be suitable as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by FDA. Such a donor is considered no longer deferred.

[66 FR 31164, June 11, 2001]

§ 610.42 Restrictions on use for further manufacture of medical devices.

(a) In addition to labeling requirements in subchapter H of this chapter, when a medical device contains human blood or a blood component as a component of the final device, and the human blood or blood component was found to be reactive by a screening test performed under § 610.40(a) and (b) or reactive for syphilis under § 610.40(i), then you must include in the device labeling a statement of warning indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified communicable disease agent(s).

(b) FDA may approve an exception or alternative to the statement of warning required in paragraph (a) of this section based on evidence that the reactivity of the human blood or blood component in the medical device presents no significant health risk through use of the medical device.

[66 FR 31164, June 11, 2001]

§ 610.44 Use of reference panels by manufacturers of test kits.

(a) When available and appropriate to verify acceptable sensitivity and specificity, you, a manufacturer of test kits, must use a reference panel you obtain from FDA or from an FDA designated source to test lots of the following products. You must test each lot of the following products, unless FDA informs you that less frequent testing is appropriate, based on your consistent prior